DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 17, 2015

Coho Technology Co., Ltd.
Ms. Jacky Hsieh
General Manager
21 Dafeng Street
Luju Township, Taoyuan County 33860
Taiwan

Re: K140836
Trade/Device Name: Zibone Zirconia Blocks
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: April 10, 2015
Received: April 22, 2015

Dear Ms. Hsieh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K140836

Device Name: Zibone Zirconia Blocks

Indications for use:

"Zibone Zirconia Blocks" are intended for CAD/CAM fabrication of full ceramic dental restorations such as copings, crowns, inlays, onlays, veneers, and bridges of 3 or less units.

Prescription Use V AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510 (K) Summary

This summary of 510(K) substantial equivalence information is being submitted in accordance with the requirements of SMDA and 21 CFR 807.92

1. Submitter:

Coho Technology Co., Ltd
Contact Name: Jacky Hsieh
Address: No.21 Dafeng St, Luju Township,
Taoyuan County, Taiwan R.O.C 33860
Email:jackyhsieh@coho.com.tw
Tel: +886-3- 3112203
Fax: +886-3-3125626

2. Summary Preparation Date: Feb 14, 2014

3. Device Identification:

Trade name:	Zibone Zirconia Blocks
Classification Name	Porcelain powder for clinical use
Common name:	Zirconia Blanks/Blocks
Product code:	EIH
Regulation No.:	21CFR 872.6660
Classification:	Class II

4. Legally marketed equivalent device:

A&E Zirconia Blanks
510 (K) number: K100145

5. Device Description:

"Zibone Zirconia Blocks" are made from partially sintered zirconium oxide. The devices are to be CNC machined to construct dental restorations and substructures such as crowns and bridges with the aid of CAD/CAM technology.

The devices are in cylinder forms with a constant diameter of 98mm and variety of heights from 12 to 20 mm, and in rectangular bar forms with various lengths and widths with the height of 16mm.

6. Intended Use:

"Zibone Zirconia Blocks" are intended for CAD/CAM fabrication of full ceramic dental restorations such as copings, crowns, inlays, onlays, veneers, and bridges of 3 or less units.

7. Technological characteristics:

"Zibone Zirconia Blocks" and the predicate device have the same intended use and are made from the same zirconium oxide material. Furthermore, the material conforms to international standard *ISO 6872:2008 Dentistry – Ceramic materials* to guarantee biocompatibility and necessary mechanical strength.

	Subject Device (K140836)	Predicate Device (K100145)
Major chemical component	ZrO2	ZrO2
Indications for Use	“Zibone Zirconia Blocks” are intended for CAD/CAM fabrication of full ceramic dental restorations such as copings, crowns, inlays, onlays, veneers, and bridges of 3 or less units.	"A&E zirconia blanks are pre-sintered metal-free zro2 ceramic blanks (y-tzp). They are specifically designed for fabrication of sub-frames for the construction of dental prosthetic (e.g, crowns and bridges restorations etc) with the aid of manual copy-milling machines and cad/cam systems
Method of fabrication	CAD/CAM Systems	CAD/CAM Systems and manual milling machines
Shape	Cylinder and Bar shapes	Cylinder
Types of restorations	Coping/Crown/Inlay/Onlay/ Veneer/Bridge	Coping/Crown/Inlay/Onlay/ Veneer/Bridge
Colors	White/ Color can be customized during sintering	White/ Color can be customized during sintering
Device Forming Process	Press (CIP)	Press (CIP)

The subject device and predicate device although are different in the percentage of their chemical compositions, but the major components are identical. Furthermore, tests per ISO 6872 validated the equivalence of these two devices and ensured that the subject device is suitable for its indications.

8. Non-Clinical Bench Tests:

The devices have been tested for its physical, chemical and mechanical properties such as thermal expansion, chemical solubility, 4-point bending strength, and radiation tests per ISO 6872, in addition to the biocompatibility evaluations such as cytotoxicity per ISO 10993-5 and ISO 10993-11, sensitization and irritation per ISO 10993-10, and pyrogen tests per ISO 10993-11 and USP 151.

9. Conclusion:

Based on similar chemical composition, intended use, technological characteristics, physical properties testing, and favorable biocompatibility results, Zibone Zirconia Blocks are substantially equivalent to the predicate device.